

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-10-030

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

NÜVE SANAYİ MALZEMELERİ İMALAT ve TİCARET ANONİM ŞİRKETİ

Saracalar Mahallesi Saracalar Kümeevleri No:4/2 Akyurt Ankara, Turkey

Products: Steam Sterilizers, Dry Heat Sterilizers, Blood Bank Refrigerators, Deep Freezers, Platelet Incubators

The products defined at the enclosure which is the part of this certificate and contains one page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number:M.3158.10Date of first issue:31 May 2010Date of last issue:19 February 2019Revision Number:08Expiry Date:18 February 2024

Head of Notified Body

Kiwa Certification Services Inc. ITOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey Tel.: +90 216 593 25 75, Fax: +90 216 593 25 74 Web: www.kiwa.com.tr, e-mail: posta@kiwa.com.tr

19 February 2019, Istanbul, Turkey







EU-type Examination Certificate

This is to certify that the product listed below conforms to the requirements of the Pressure Equipment Directive 2014/68/EU

Annex III Module B(prod)

NÜVE SANAYi MALZEMLERi iN Saracalar Mah. Saracalar Kümeev Akyurt /Ankara /Turkey		
, any arc , and a , rankey	vleri No:4/2	
150, NC 150D, NC 40M, N NC 570, NC 570D, NC 710	NC 90M, NC 300, N 0, NC 710D;	C 430, NC 430D,
7118, N 8040, N 8036, N 6871, N 7987, I	N 8457, N 7539, N 8359, N 8	
n/a		
PS = 3 bar (for NC 23S, NC 23B, NC 325	S PS = 2,6 bar)	
Max 144 °C (for NC 23S, NC 23B, NC 32 EN 13445	2S Max 140 °C)	
HPiVS/P1057-048-DR01 to DR04		
by HPi Verification Services Ltd which i	s a body notified to the E	
	150, NC 150D, NC 40M, N NC 570, NC 570D, NC 710 Steam generator Range: N 570, NC 710. N 8467, N 8466, N 8468, N 8475, N 8456 7118, N 8040, N 8036, N 6871, N 7987, N 8515 Rev.0 dated 19 Oct 2017; N 849 N 8491 Rev.0 dated 26 Sep 2017 n/a PS = 3 bar (for NC 23S, NC 23B, NC 326 Max 144 °C (for	N 8467, N 8466, N 8468, N 8475, N 8458, N 8460, N 8463, N 8462, N 7118, N 8040, N 8036, N 6871, N 7987, N 8457, N 7539, N 8359, N 8 N 8515 Rev.0 dated 19 Oct 2017; N 8497 Rev.0 dated 05 Oct 2017; N 8491 Rev.0 dated 26 Sep 2017 n/a PS = 3 bar (for NC 23S, NC 23B, NC 32S PS = 2,6 bar) Max 144 °C (for NC 23S, NC 23B, NC 32S Max 140 °C) EN 13445

This Certificate is issued following the assessment of a representative sample of the Pressure Equipment detailed above in accordance with the provisions of the above regulations. The equipment must be subject to an appropriate conformity assessment module during manufacture prior to the CE Mark being affixed.



Managing Director

Technical Manager

CE

EU Notified Body No. 1521 Company registered in England #7217086

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 Tel
 +44 1491 822818

 Fax
 +44 700 600 6831

 Email
 enquiries@eucertification.com

 www.eucertification.com

HPI Verification Services Ltd. The Manor House Howbery Park, Wallingford OX10 8BA, United Kingdom

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NC 40M / 90M Laboratory Steam Sterilizers



NC 40M/90M

LABORATORY STEAM STERILIZERS

NC 40M / NC 90M laboratory steam sterilizers are specially designed for the steam sterilization of liquid and culture media and also convenient for the sterilization of any labware such as glass and plastics and unpacked solid materials in the laboratories of hospitals, universities and pharmaceutical, food, beverage, dairy and biotechnology industries.

STANDARD FEATURES FOR LIQUID STERILIZATION

- Flexible temperature sensor to measure the temperature of the liquid load directly as the time required to reach the sterilization temperature of liquid is longer compared to solid loads.
- Cooling function with ambient air ventilation over the chamber that decreases the cooling time of liquid loads to the one third of time spent by conventional systems.
- Condensation of steam at the end of the cycle by means of air ventilated cooling system to prevent a sudden drop in the chamber pressure which causes re-boiling.

WELL PRESERVED SENSITIVE MATERIALS

- Second temperature sensor active for solid load sterilization.
- Controlled steam discharge by fractionated exhaust.
- Programmable exhaust rate against sudden temperature and pressure drop to preserve sensitive materials such as glass.







RELIABLE AND POWERFUL CONTROL SYSTEM: N-Smart[™]

- Maximum information with highly visible 4,3" colourful LCD display
- Four context-sensitive function keys for versatile & easy use
- Password protected menu to secure run parameters and data
- With 5 Language options: Turkish, English, French, Russian, Spanish
- Icons to make the operations easier for immediate understanding

EASY STERILIZATION

• Five pre-set programs which guarantee safe sterilization of the treated material.

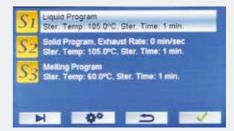
Liquid	121°C	15 minutes
Liquid	121°C	20 minutes
Solid	121°C	20 minutes
Solid	134°C	20 minutes
Solid Quick	134°C	4 minutes

- Two free programs for liquid and solid and a special program for melting purposes which the user can program easily.
- Delayed start function with real time which allows the users to get their samples sterilized on time as they arrive to the laboratory.
- Programmable pre-heating.



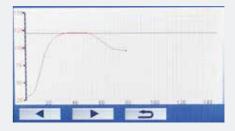






FULL TRACEABILITY AND REMOTE ACCESS

- Operating parameters can be tracked graphically against time
- Massive data storage with internal memory which stores the records of last 500 cycles detailed and 29.500 cycles as summary
- Memory for the last 100 failures
- USB port to record the operated cycles in the memory to a memory stick
- Possibility of PC Connection through USB / RS 232 port
- Ethernet port for remote access through internet by means of optional NüveCloser™ software
- NuveCloser[™] allows access to operating parameters, memory ,failure history and other technical parameters
- Optional panel type printer to keep the records of the sterilization cycle

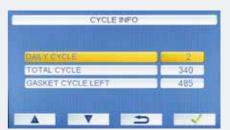


		0		BRROR
00001	02.10.15	15:33	Liquid P1	21 -
00002	02.10.15	10:50	Solid P4	V
00003	01.10.15	15:01	Solid P4	V
00004	01.10.15	14:03	Solid P4	V +++
00005	01.10.15	11:44	Solid P4	

00001	01 10.15	11:37	POWER FAILURE
0002	30.09.15	09:50	HIGH PRESSURE
0003	30.09.15	09:10	HIGH PRESSURE
00004	29.09.15	14:17	HIGH PRESSURE
00005	29.09.15	13:55	NO WATER

All Cycles	
Error Records	
 Memory Stick Records	
Cycle Info	

Program: Liqui Preheating: 12	3.0°C	
Phase.	Temp. • C	Time Min.
St art	27.0	00:00:00
Heating	90.0	00:14:11





SAFETY OVER STANDARDS

- Password protected control system, service and calibration menu
- Lid safety system
- Lid cannot be opened when the chamber is pressurized
- Program cannot be operated if the lid is open
- Lid can be opened when the liquid temperature is below 80°C after liquid sterilization
- Lid can be opened when the chamber temperature is below 90°C after solid sterilization
- Comprehensive self-diagnostic system to provide the information regarding possible system malfunction. The self-diagnostic system warns user in case of:
- Broken temperature sensors
- Over temperature
- Heater failure
- Low temperature
- Overpressure
- Exhaust tank failure
- Lack of water
- High preheating temperature
- Colour of the display changes to red in case of any alarm condition along with an audible alarm
- Remote failure diagnostic by means of NüveCloser[™] software
- · Sending e-mails up to five e-mail addresses with the details of failure
- Optional AlerText[™] SMS alarm system for ultimate security
- Safety valve against over pressure
- Manometer to follow the chamber pressure
- Chamber manufactured according to PED 2014/68 EC
- Validation port as standard











TECHNICAL SPECIFICATIONS

	NC 40M	NC 90M	
Chamber Volume	40 litres	90 litres	
Temperature Range	105°C - 135°C		
Control System	N-Smart™ Control System		
Display	4,3" Colourful LCD Display		
No of Preset Programs	2 For Liquids, 3 For Solids		
No of Free Programs	1 For Liquids, 1 For Solids		
Melting Program Temperature Range	60°C -	100°C	
Timer for Free Programs	1-300 minutes		
Timer for Melting Program	1-60 minutes		
Delayed Start Timer	Programmable With Real Date and Time		
Chamber Material	Stainless Steel		
No. of Baskets	2 pcs. (Ø 295x242 mm)	3 pcs. (Ø 360x242 mm)	
Power Consumption	2.500 W	7.000 W	
Power Supply	220 V 50/60 Hz.	400 V 50/60 Hz., 3 phases+N+G	
Chamber Dimensions (Diameter x Depth) mm	Ø 320x520	Ø 396x750	
External Dimensions (WxDxH) mm.	560x600x985	680x660x1050	
Packing Dimensions (WxDxH) mm.	570x660x1200	730x760x1200	
Net / Packed Weight kg.	80 / 91	113 / 134	

Loading Capacity for NC 40M Erlenmeyer Flasks

250 ml	500 ml	1000 ml	2000 ml	3000 ml	5000 ml
3x8 pcs.	2x4 pcs.	2x3 pcs.	1 pc.	1 pc.	1 pc.

Loading Capacity for NC 40M Schott-Duran Bottles

250 ml	500 ml	1000 ml	2000 ml	3000 ml	5000 ml
3x12 pcs.	2x8 pcs.	2x5 pcs.	3 pc.	1 pc.	1 рс.

Loading Capacity for NC 90M Erlenmeyer Flasks

250 ml	500 ml	1000 ml	2000 ml	3000 ml	5000 ml
4x12 pcs.	3x7 pcs.	3x4 pcs.	2x3 pcs.	2x1 pc.	1 pc.

Loading Capacity for NC 90M Schott-Duran Bottles

250 ml	500 ml	1000 ml	2000 ml	3000 ml	5000 ml	10000 ml
4x18 pcs.	3x11 pcs.	3x8 pcs.	2x4 pcs.	2x1 pc.	2x1 pc.	1 pc.

FACTORY FITTED OPTIONS

NC XXMY	Panel mounted thermal printer
NC 90ME	NuveLift [™] to load/unload basket for NC 90M

OPTIONS

A 08 191	AlerText [™] GSM alarm module
A 08 212	NuveCloser [™] Software CD with 3 m. RS 232 cable

ACCESSORIES FOR OT 40L

 S 09 028
 Basket (Height : 345 mm)

 S 09 027
 Basket (Height : 242 mm)

S 09 040 Basket (Height : 160 mm) (Unperforated)

ACCESSORIES FOR OT 90L

- **S 09 034** Basket (Height : 360 mm)
- **S 09 035** Basket (Height : 242 mm)
- **S 09 041** Basket (Height : 170 mm)
- S 09 043 Basket (Height : 242 mm) (Special for NC 90ME)



NÜVE SANAYİ MALZEMELERİ İMALAT VE TİCARET A.Ş.

Saracalar Mah. Saracalar Kümeevleri No: 4/2 Akyurt 06750 ANKÅRA / TURKEY t. +90 312 399 28 30 f. +90 312 399 21 97 ISO 900 ISO 1348

